IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel* **John Underwood**	:	
Plaintiff,	:	**CIVIL ACTION NO.**
v.	:	**FILED *IN CAMERA* AND UNDER SEAL**
GENENTECH, INC. AND ROCHE HOLDINGS, INC.	:	**JURY TRIAL DEMANDED**
Defendants.	:	

QUI TAM COMPLAINT

Relator, John Underwood, by his attorneys, for his complaint against Defendants Genentech, Inc. and Roche Holdings, Inc., alleges the following:

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false statements and claims presented, or caused to be presented, or presented by the Defendants to the United States, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729-32, as amended (the "FCS").

2. Relator John Underwood is a resident of the state of North Carolina. From the start of the BioOncology franchise at Genentech in 1997, Relator was a senior manager of sales development. From 2000 until recently, he was a division sales manager employed by Defendants to whom field sales representatives reported directly. Relator currently is employed by the Defendants as a senior hospital systems specialist. John Underwood is the original source of the facts and information hereinafter set forth concerning the activities of the Defendants. The

facts averred herein are based entirely upon his personal observation and documents in his possession.

3. Defendant Genentech, Inc. is a biotechnology company incorporated in the state of California and rechartered in the state of Delaware. Genentech is a biotechnology company that develops, manufactures, licenses and markets pharmaceutical products including prescription drugs falling under the jurisdiction and regulation of the United States Food and Drug Administration.

4. Defendant, Roche Holdings, Inc. is the parent company of Defendant Genentech, Inc. On information and belief, Roche Holdings, Inc. is incorporated in the state of Delaware.

JURISDICTION AND VENUE

5. The Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730.

6. This Court has jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because defendants can be found and have transacted the business that is the subject matter of this lawsuit in the Eastern District of Pennsylvania.

7. Venue is proper pursuant to 31 U.S.C. § 3732(a) in that Defendants can be found, reside in and have transacted the business that is the subject matter of this lawsuit in the Eastern District of Pennsylvania.

FACTS

8. Relator has prepared, and will provide with this complaint to the Attorney General of the United States and the United States Attorney for the Eastern District of Pennsylvania, a disclosure pursuant to 31 U.S.C. § 3730(2) of material evidence and information in his possession related to the Complaint and of which he is the original source. This disclosure supports the existence of the claims being filed or presented herein.

9. The United States Food & Drug Administration (the "FDA") is entrusted by law, 21 U.S.C. §§ 301 et seq., with the responsibility to ensure, among other things, that the American public is treated medically only with drugs that have met certain standards with respect to efficacy and safety and that are appropriately labeled.

10. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Pursuant to its rulemaking authority, the FDA has promulgated regulations that restrict the marketing efforts that a pharmaceutical company can make with respect to potential uses of its drugs over and above those uses of that product which have been specifically approved by the FDA. 21 C.F.R. § 99.1 et. seq.

11. The FDA regulations provide that "a manufacturer may disseminate written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling for an approved drug...provided that the manufacturer complies with all other relevant requirements under this part." Among the requirements are: (1) that the drug has been approved, licensed or cleared for marketing by the FDA for some purpose; (2) that the communications by the manufacturer be in the form of research published in a scientific or medical journal; (3) that it not be false or misleading or incomplete; (4) that it display if the information is being disseminated at the expense of the manufacturer; (5) that it display if any of

the authors were paid by the manufacturer; (6) that it identify any person paying for studies; (7) that the drug not pose a significant threat to public health; and (8) that it be labeled as information concerning a use that has not been approved by the FDA. 21 C.F.R. § 99.101-99.103.

12. One of Genentech's principal products is Rituximab, sold under the brand name Rituxan, a monoclonal antibody used to treat patients with non-Hodgkin's lymphoma.

13. In November 1997, Defendants received permission from the FDA to market Rituxan to physicians and other medical care providers for the purpose of treating relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkins lymphoma. In April 2001, the FDA approved a supplemental Biological License Application for retreatment of non-Hodgkins lymphoma patients with Rituxan who have relapsed following initial Rituxan therapy; use of eight weekly doses (compared to the original four) per course of treatment of non-Hodgkin's lymphoma; and for treatment of non-Hodgkins lymphoma patients with relapsed or refractory bulky disease (lesions greater than 10cm). The FDA has not approved Rituxan for any other use.

14. By the end of 2002, Defendants' sales of Rituxan for the approved purposes amounted to close to 30% of Defendants' total sales of Rituxan. The balance, in excess of 70%, constituted sales for purposes other than that approved by the FDA. Defendants' total sales of Rituxan in 2002 were approximately $1.07 billion.

15. The practice of advocating the use of a drug to treat conditions not specifically approved by the FDA is called "off-label marketing." Unless performed in accordance with the FDA regulations described in paragraph 11 above, it is illegal when engaged in by drug

companies, but not illegal when engaged in by independent physicians based on their own independent medical judgment.

16. After achieving FDA approval of Rituxan, Defendants formed a scheme to increase the sales of Rituxan while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of Rituxan. The scheme consisted of an elaborate and clandestine promotion of off-label uses of Rituxan, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency.

17. In particular, Genentech promoted the following off-label uses of Rituxan: for front-line therapy, alone or in combination, in treating low-grade non-Hodgkins lymphoma; for front-line therapy, alone or in combination, for chronic lymphocytic leukemia; for front-line therapy, alone or in combination, for treating intermediate/high-grade non-Hodgkins lymphoma; alone or in combination for patients with relapsed chronic lymphocytic leukemia; alone or in combination for treating intermediate/high-grade non-Hodgkins lymphoma; alone or in combination for patients with the autoimmune disease, idiopathic thrombocytopenic purpura, also known as immune thrombocytopenic purpura; for patients with autoimmune hemolytic anemia; for patients with Waldenstrom's macroglobulinemia; for patients with Mantle cell lymphoma; for patients with rheumatoid arthritis; for patients with bone marrow transplants; for patients with pure red cell aphasia; for patients with Hodgkins disease; for patients with systemic lupus erythematosus; and generally for maintenance therapy and front-line therapy in any of the above listed lymphomas or leukemias.

18. Between approximately January 2000 and at least December, 2002, Defendants have, passively and explicitly, encouraged oncologists and other physicians and medical providers to bill Medicare and other government reimbursement programs for Rituxan for "off-

label" uses, and to represent thereby that the off-label use for which reimbursement is being requested was the result of the medical providers' independent and impartial medical judgment. Defendants did this while knowing that they were, in fact, surreptiously advocating the use of Rituxan for off-label purposes through means other than those approved by FDA in its regulations and that these means were designed to evade the Defendants' responsibility to present a balanced view of Rituxan, its risks and benefits.

19. Among the methods by which Defendants accomplished this were the following:

(a) Defendants retained physicians to act as "independent" speakers on behalf of Rituxan and its off-label uses, knowing full well that these speakers were not, in fact, truly independent in that they received tens of thousands of dollars every year for speaking to other physicians about off-label uses of Rituxan;

(b) Defendants exerted significant pressure on their sales representatives, including Relator, to increase off-label uses of Rituxan by all possible means;

(c) Defendants devised and conducted "Selling Skills Workshops" for all of its sales representatives devoted to non-label uses;

(d) Defendants disguised the subject matter of "seminars" for physicians by assigning general titles to speeches that, in fact, were exclusively devoted to off-label marketing;

(e) Defendants established and paid a third-party contract organization, Oncology Education Continuum ("OEC"), to set up and conduct off-label presentations, including slide shows, by physicians to other physicians. Defendants instructed their sales representatives to only use OEC for off-label presentations. The presentations were created by Defendants' sales and marketing department with little or no substantive contribution by the third-party contract organization other than serving an administrative function and as a conduit for funds paid by Defendants to the physician-speaker. Defendants failed to disclose that programs were not developed by the presenting physicians;

(f) Defendants utilized "advisory boards" whereby rotating physicians were invited and paid, purportedly by medical science liaisons at Genentech but actually by the sales and marketing department, to attend "medical education seminars" about off-label uses of Rituxan at luxurious locations, and Defendants provided financial incentives to their sales representatives to get their physician-customers who sell the most Rituxan to attend;

(g) Defendants attempted to get Medicare and other government reimbursement programs to reimburse physicians for off-label uses of Rituxan by placing physicians who utilized Rituxan for off-label purposes on advisory committees to such reimbursement programs and organizing letter writing campaigns by physicians to these reimbursement programs demanding that the programs reimburse physicians for the off-label uses;

(h) Defendants illegally directly solicited physicians to use Rituxan for off-label uses;

(i) Defendants failed to disclose that favorable articles were written by physicians paid by Defendants;

(j) Defendants made false statements to physicians and the Veterans Administration concerning the efficacy and safety of Rituxan for off-label uses;

(k) Defendants' sales department paid kick-backs to physicians which were frequently disguised as consultantships although unrelated to any scientific or educational activity. The kickbacks have taken the form of cash payments, travel benefits, entertainment, and other benefits. Defendants have internal guidelines for the award of these benefits to physicians which are based in large part on the number of off-label prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Rituxan for off-label uses; and

(l) Defendants actively trained their employees, including Relator, in methods of avoiding detection of their illegal activities by the FDA. Defendants stated their goal was to avoid detection by the FDA.

20. Another Genentech product is Trastuzumab, sold under the brand name Herceptin. In September 1998, the FDA approved Herceptin, a humanized antibody, for treatment in combination with paclitaxel of patients with metastatic breast cancer whose tumors overexpress the HER2 (human epidermal growth factor receptor 2) protein.

21. The Medicare and Medicaid Fraud and Abuse Statute was first enacted under the Social Security Act in 1977. The statute imposes criminal penalties on whomever violates the Anti-Kickback Provision and

> offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2)(B). This statute prohibits the mere act of offering such illegal remuneration, regardless of whether the inducement is ultimately accepted by the buyer. Such inducements are harmful to the federal government because they encourage unnecessary treatments, influence the free exercise of medical judgment by providers, limit patient options and lead to higher federal payments for medical services.

22. As part of its nationwide program of promotion of Herceptin, Defendants have established a system of kick-backs to physicians who prescribe large amounts of Herceptin.

(a) The kickbacks have taken the form of cash payments initially paid at over $1000 per patient and increasing over time to $3100 per patient given through the guise of paying physicians for screening, enrolling and documenting patients in the "Her First" clinical trial. These payments were in addition to any actual costs incurred in connection with screening, enrolling and documenting patients in the "Her First" clinical trial.

(b) Instead of medical science liaisons, sales representatives were illegally recruiting patients for clinical studies and ensuring physicians were paid for the patients. The Her-First Study Reference Binder was given to sales representatives to help them recruit accounts. These sales representatives were given bonus incentives for the number of accounts and for the number of patients enrolled in these accounts. The sales representatives were also given incentives to promote peer to peer physician lectures to increase Herceptin sales.

(c) Defendants train their employees to actively conceal the illegal kick-backs for Herceptin. In fact, the sales team, including Relator, was warned in writing not to put anything in writing regarding the economic incentives in place for the "Her First" clinical trial for Herceptin.

COUNT I
DELIBERATE AVOIDANCE OF FDA REGULATIONS/ MEDICARE AND MEDICAID FINANCED SALES -- RITUXAN

23. Relator realleges and incorporates by reference herein the allegations contained in paragraphs 1 - 22 above.

24. A significant percentage of patients who use or have used Rituxan for off-label purposes are persons who are over the age of 65 whose prescriptions are paid for in whole or in part by state administered medical assistance programs which receive 90% reimbursement from the federal government, to wit, Medicare and Medicaid.

25. The Medicare and Medicaid programs of the federal government include detailed provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for full federal participation price controls on prescription drugs, and drug manufacturer rebate agreements. These laws and regulations include, inter alia, as set forth as 42 U.S.C. § 1395y(c) , that no federal payment shall be made in the case of a prescription drug for which the FDA has issued a notice of hearing regarding the effectiveness of the drug. Thus, the taking of a regulatory action by the FDA against the sale and promotion of a drug will, in circumstances, immediately interrupt the flow of federal funds for reimbursements of prescriptions written for the drug.

26. Promotion of off-label usage of a drug constitutes "labeling" as defined by the food and drug laws of the United States. It is reasonably certain, and Defendants are aware, that if the FDA became aware of its extensive program of illegal promotion of off-label uses of Rituxan, the FDA would take administrative action against Defendants, including, among other things, a notice of hearing regarding the effectiveness of Rituxan for the promoted off-label uses. Such a notice would, by federal statute, instantly interrupt the flow of federal funds for reimbursement for off-label prescriptions. In fact, Defendants recognize how expensive the repercussions would be from being caught by the FDA based on their $50 million settlement with the United States in 1999 for promoting off-label use of the growth hormone protropin.

27. Defendants have, as alleged, actively concealed its off-label promotion of Rituxan from the FDA with specific training to its employees to do so. Said active concealment is motivated by the desire to, and has had the affect of, preserving the flow of federal funds to reimburse Rituxan prescriptions. Said active concealment constitutes a pattern of fraudulent conduct through which federal payments are derived, and constitutes False Claims within the meaning of 31 U.S.C. § 3729.

COUNT II
FALSE STATEMENTS TO PHYSICIANS -- RITUXAN

28. Relator realleges and incorporates by reference herein the allegations contained in paragraphs 1 - 27 above.

29. As part of its illegal off-label promotion of Rituxan, Defendants have instructed and caused its sales personnel and its medical employees to make false statements to physicians, deliberately omit material information to physicians, and to provide physicians with written materials containing false statements and omissions, concerning the safety and efficacy of Rituxan for off-label uses. These statements were made with the intent of, and had the effect of, inducing physicians to increase their off-label prescription of Rituxan. This increased off-label prescription of Rituxan caused harm to the federal government by increasing the number of Medicare and Medicaid claims for Rituxan prescriptions.

30. Defendants' false statements and deliberate omissions of material information to physicians were a pattern of fraud designed to induce payments by the federal government, and constituted a violation of the FCS within the meaning of 31 U.S.C. § 3729.

COUNT III
ILLEGAL KICKBACKS -- RITUXAN

31. Relator realleges and incorporates by reference herein the allegations contained in paragraphs 1 - 30 above.

32. Federal laws and regulations governing the Medicare and Medicaid programs prohibit kick-backs to physicians and medical care providers, in particular 42 U.S.C. § 1320a-7a (civil penalties), 42 U.S.C. § 1320a-7b (criminal penalties) and 42 C.F.R. § 1003.100 et. seq. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

33. As part of its nationwide program of off-label promotion of Rituxan, Defendants have established a system of kick-backs to physicians who prescribe large amounts of Rituxan as described in paragraph 19 and its subparts.

34. These kick-backs are strictly illegal and have had the effect of greatly increasing the amount of Rituxan prescriptions, and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by Medicare and Medicaid. The payment of these kick-backs represents the inducement of federal payments through a pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

COUNT IV
DIRECT SALES TO VETERANS ADMINISTRATION -- RITUXAN

35. Relator realleges and incorporates by reference herein the allegations contained in paragraphs 1 - 34 above.

36. Defendants have sold, and are selling, significant quantities of Rituxan to the Veterans Administration for off-label uses.

37. Defendants are conducting, and have conducted, illegal direct promotion of off-label uses of Rituxan directly to the Veterans Administration. Defendants have, on a nationwide basis, illegally and directly promoted off-label uses of Rituxan to Veterans Administration physicians and pharmacists. These illegal promotional activities have resulted in greatly increased use of Rituxan by the Veterans Administration. Defendants' sales to the Veterans Administration have been derived through a pattern of fraud, to wit, the deliberate violation of the laws and regulations of the United States and the deliberate active concealment of those violations. Defendants' deliberate violation of federal law used as a method of procuring sales of drugs to an agency of the federal government constituted a False Claim within the meaning of 31 U.S.C. § 3729.

38. Defendants' medical, sales and marketing personnel have promoted the off-label use of Rituxan by the Veterans Administration by deliberate omissions of material information and making false and unfounded claims to Veterans Administration physicians and pharmacists concerning the safety and efficacy of Rituxan for off-label uses. These claims of safety and efficacy for off-label uses are false and made with reckless disregard of the truth or deliberately omit material information. Defendants' use of false statements concerning the safety and efficacy of Rituxan used as a means of procuring sales to the Veterans Administration constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT V
VIOLATING STATE FORMULARIES/
MEDICARE AND MEDICAID -- RITUXAN

39. Relator realleges and incorporates by reference herein the allegations contained in paragraphs 1 - 38 above.

40. Under the statutes and regulations establishing the Medicare and Medicaid programs, the individual states are permitted to establish drug utilization review boards and formularies which define those prescription drugs and their uses for which a state agency will make reimbursement under their Medicare programs. Federal law, in particular 42 U.S.C. § 1396r-8, requires a state formulary to include medically accepted uses of prescription drugs by reference to the publications set forth, in § 11, supra.

41. Many state Medicare agencies intend not to reimburse for prescription drugs for uses not set forth in the publications referred to in § 11, supra, in that the states do not intend to spend money on prescriptions not recognized as medically necessary in sources specified by federal law. However, many states lack the technical ability to monitor precisely for medical diagnoses in the case of individual prescriptions, and thus lack the technical ability to reject reimbursement for off-label uses of prescription drugs which are not medically accepted according to the federally specified publications. This lack of technical ability represents a loop-hole in the structure of the Medicare and Medicaid programs.

42. Defendants have recognized and aggressively exploited this loop-hole by means of a direct, illegal, nationwide program of promotion of off-label use of Rituxan by physicians. Defendants have conducted this program of promotion knowing that prescriptions for Rituxan are generally reimbursed by state Medicare programs even though individual prescriptions for Rituxan fall outside of state formularies because they are not medically proven through the conducting of unbiased trials.

43. Defendants' aggressive, illegal scheme of off-label promotion has induced federal payments through a pattern of fraudulent conduct by causing the states, and thus the federal

government, to pay out sums to claimants they did not intend to benefit. Defendants' conduct constitutes a violation of the FCS within the meaning of 31 U.S.C. 3729.

COUNT VI
AVOIDING PRICE CONTROLS
BASED ON THERAPEUTIC EQUIVALENCY -- RITUXAN

44. Relator realleges and incorporates by reference herein the allegations contained in paragraphs 1 - 43 above.

45. The federal laws establishing the Medicare and Medicaid programs contain drug price controls based on therapeutic equivalencies, as established by the FDA in an official publication (42 U.S.C. § 1396r-8). Defendants' illegal program of off-label promotion and avoidance of proper FDA procedures for approval of a new drug use has resulted in the lack of any classification of Rituxan for therapeutic equivalency as to its off-label uses. As a result, Rituxan has not been subject to federal Medicare price limits based on therapeutic equivalency.

46. The federal government has been harmed by this avoidance of a rating of Rituxan for therapeutic equivalency because other less expensive drugs are capable of conferring the same benefit as Rituxan for various off-label uses. If Rituxan were properly rated for therapeutic equivalency, the states and the federal government would be able to achieve the same benefits for less money.

47. Defendants' illegal scheme of off-label promotion is a deliberate avoidance of federal price controls based on therapeutic equivalency, and constitutes inducement of federal payments through a pattern of fraudulent conduct and constitutes a False Claim within the meaning of 31 U.S.C. § 3729.

COUNT VII
ILLEGAL KICKBACKS -- HERCEPTIN

48. Relator realleges and incorporates by reference herein the allegations contained in paragraphs 1 - 47 above.

49. Federal laws and regulations governing the Medicare and Medicaid programs prohibit kick-backs to physicians and medical care providers, in particular 42 U.S.C. § 1320a-7a (civil penalties). 42 U.S.C. § 1320a-7b (criminal penalties) and 42 C.F.R. § 1003.100 et. seq. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

50. As part of its nationwide program of promotion of Herceptin, Defendants have established a system of kick-backs to physicians who prescribe large amounts of Herceptin as described in paragraph 22 and its subparts.

51. These kick-backs are strictly illegal and have had the effect of greatly increasing the amount of Herceptin prescriptions, and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by Medicare and Medicaid. The payment of these kick-backs represents the inducement of federal payments through a pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

WHEREFORE, Relator demands judgment in its favor and against Defendants as follows:

(a) For an amount equal to three times the amount of damages the United States has sustained because of each Defendant's actions, plus a civil penalty of not less than $5,000.00 nor more than $10,000.00 for each violation of 31 U. S. C. § 3729;

(b) For a judgment in favor of Relator, as a Qui Tam Plaintiff, in the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of law;

(c) For a judgment in favor of Relator, as a Qui Tam Plaintiff for all costs of this action, including, but not limited to, attorneys' fees, expert fees, and court costs; and

(d) For a judgment in favor of Plaintiff and Relator for such other and further relief as the Court deems just and proper.

Respectfully submitted,

Elizabeth K. Ainslie (Attorney I.D. 35870)
Theresa E. Loscalzo (Attorney I.D. 52031)
Jennifer Nestle (Attorney I.D. 84657)

SCHNADER HARRISON SEGAL & LEWIS LLP
1600 Market Street, Suite 3600
Philadelphia, Pennsylvania 19103-7286
(215) 751-2000

DATED: July 3, 2003

Certificate of Service

I, Stephenie W. Yeung, hereby certify that on this 3rd day of July, 2003 I caused a copy of Relator's Qui Tam Complaint to be served by hand delivery upon the following:

Virginia Gibson
Special Assistant United States Attorney
United States Attorney's Office for the
Eastern District of Pennsylvania
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106-4476
Attorneys for the United States

In addition, a copy of Relator's Qui Tam Complaint was served by certified mail, return receipt requested upon the following:

John Ashcroft, Esquire
Attorney General
United States Department of Justice
950 Pennsylvania Ave, NW
Washington, D.C. 20530-0001

Stephenie W. Yeung